CPSC-IAG-02-1407

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

INTERAGENCY AGREEMENT

1. IAG NO. (FDA)	2. TYPE OF AGREEMENT	3. MODIFICATION NO.
224-02-2740	☒ New ☐ Mod ☐ Administrative ☐ No Cost Ext.	

4. TITLE OF PROJECT

Choking Hazard Potential of Konjac-Gel Containing Candies and Related Products

5. DESCRIPTION OF WORK - ATTACHED	6. AMOUNT	
See attached	$15,000	
7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY Consumer Product Safety Commission Directorate for Health Sciences, Room 600-20 Washington, DC 20207	LIAISON NAME: Sandra E. Inkster, Ph.D.	PHONE NO. (301) 504-0994
8. NAME AND ADDRESS OF PARTICIPATING FDA UNIT Food and Drug Administration Center for Food Safety & Applied Nutrition, 5100 Paint Br. Pky. College Park, MD 20740-3835	LIAISON NAME: Mark Hackman	PHONE NO. (301) 827-7527

9. PERIOD OF AGREEMENT — FROM: October 1, 2001 — THROUGH: September 30, 2002

This agreement may be terminated by either party upon a thirty day advance written notice.

10. AUTHORITY (FDA)

☒ Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535
☐ Section 301 of the Public Health Service Act (42 USC 241)
☐ Other (specify) _____

11. AUTHORITY *(Other Agency)*

12. FDA FUNDING INFORMATION

☒ Increase from $0 by $15,000 to $15,000
☐ Decrease from _____ by _____ to _____

Appropriation: 7520600
CAN: 2-6991990-F-63342
PMS: 223152/10
Object Class: 25.38

13. Administrative billing requirements will comply with GAO Policy and Procedures, Title 7, Section 8.4

☒ Billing: X OPAC system FDA ALC 75060099 Other Agency ALC 61-00-0001

☐ _____ SF 1080 - FDA Accounting (HFA-120) 5600 Fishers Lane, Rockville, MD 20857

14. PARTICIPATING AGENCY FUNDING INFORMATION *(This block must be completed if funding is being provided to the FDA)*

a. Legal authority for the acquisition of supplies/services exists within your agency.
b. This action does not conflict with any other agency's authority or responsibility.

15. PARTICIPATING AGENCY IS

☒ Required to sign ☐ Not required to sign

16. FDA ACCEPTANCE	17. PARTICIPATING AGENCY ACCEPTANCE
NAME: Peggy L. Jones	NAME: Donna Hutton
TITLE: Grants Management Officer, FDA	TITLE: Contracting Officer
DATE: 8/22/02	DATE: 8/19/02

FDA 3443 (2/97)

EF

INTERAGENCY AGREEMENT

BETWEEN

THE UNITED STATES FOOD AND DRUG ADMINISTRATION;

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

AND

THE UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION

I. Introduction:

The U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, hereinafter referred to as FDA/CFSAN, and the U.S. Consumer Product Safety Commission, hereinafter referred to as CPSC, hereby agree that CPSC shall provide to FDA/CFSAN expert opinions regarding the choking hazard potential of konjac gel candies and related product samples. This will include but not be limited to Konjac mini-cup gel candies and will allow FDA/CFSAN to use these opinions in accordance with the terms and conditions set forth below.

II. Title:

Choking Hazard Potential of Konjac Gel-Containing Candies and Related Products

III. Purpose:

To establish an Interagency Agreement (IAG) between the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (FDA/CFSAN) and the United States Consumer Product Safety Commission (CPSC) for CPSC Staff Physiologists to provide to FDA/CFSAN expert opinions regarding the choking hazard potential of Konjac gel-candies (also known as conjac, konnyaku, glucomannan) and related product samples.

IV. Background:

A. The Food and Drug Administration enforces the Food Drug and Cosmetic Act (hereinafter, the "FDCA" which is found in Title 21 of the United States Code (21 USC). Under the FDCA, the term "food" means - (1) articles used for food or drink for man or other animals, (2) chewing

gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f).

The FDCA prohibits engaging in or causing the following acts: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded; (b) The adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce; (c) The receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. 21 U.S.C. § 331. The FDCA deems food adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. 21 U.S.C. § 342(a)(3).

FDA has been alerted to several fatal choking incidents within the U.S. as well as reports of choking fatalities in Canada, United Kingdom, Japan, Australia and Hong Kong. FDA/CFSAN is concerned about the safety of certain food products, namely Konjac mini-cup gel candies (also known and labeled as Conjac Coconut Jelly, conjac, konnyaku and glucomannan) because these products pose a serious choking hazard.

B. The CPSC administers the Federal Hazardous Substances Act (hereinafter, the "FHSA"), which requires determination of hazards posed by diverse consumer products. Several regulations have been developed under the FHSA that specifically address the choking hazard potential of various non-food consumer products which are intended for young children (e.g., rattles, pacifiers, small balls, latex balloons, and toys and articles intended for children under three years old. Physiologists in CPSC's Directorate for Health Sciences (HS) are familiar with the physiology and anatomy of the airways, the medical literature on choking hazards and the characteristics of objects involved in fatal and non-fatal choking incidents in young children. In support of the CPSC's compliance program, HS Physiologists routinely provide choking hazard assessments of diverse, non-food products intended for use by young children.

C. In mid-August 2001, FDA/CFSAN requested CPSC staff's assistance in evaluating the potential choking hazard associated with the konjac gel food/candy products. In response, CPSC HS Physiologists provided FDA/CFSAN with a memorandum entitled, *Gel Candies Containing Konjac*, dated September 6, 2001 (by SE Inkster, SW Nakamura, JR Goldsmith). The memorandum briefly discussed the physiology of choking and described generic characteristics associated with choking hazards. Furthermore, it provided HS Physiologists' expert opinion that some konjac gel candy samples (provided by FDA/CFSAN) posed a serious choking hazard to young children and older persons, particularly

those candies packaged in containers similar to individual liquid coffee creamer servings.

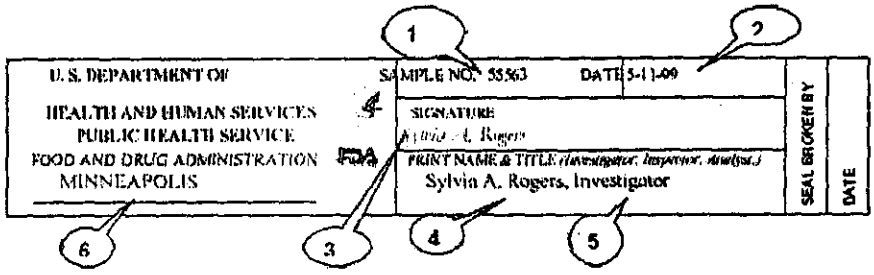
D. FDA/CFSAN subsequently issued two public warnings and an import alert. In addition, FDA monitored several recalls concerning different brands of konjac gel-containing candies. However, FDA/CFSAN anticipates that it will likely have future need of CPSC's HS Physiologists' expertise to provide further assistance in evaluating the choking hazard potential of various samples related to the konjac-gel containing candy issue.

E. With this IAG, CPSC will agree to provide FDA/CFSAN with CPSC HS Physiologists' expert opinions on choking hazards, in support of FDA/CFSAN's compliance program. Likewise, FDA/CFSAN will inform CPSC staff of choking deaths and injuries associated with the subject products.

V. Description of Work:

A. FDA/CFSAN will provide:

1. Samples of products for which a choking hazard evaluation is needed, plus documentation providing details of each sample and a unique sample identification number. When FDA collects an official sample, the product is identified with a unique sample collection number, date of collection and the initials of the FDA employee collecting the sample. The sample collection number is used to track the sample from collection to laboratory analysis, and for reporting the analytical results to the respective compliance branch. FDA currently tracks official samples by the Field Activity Compliance Tracking System (FACTS). FDA's sampling protocol requires that official samples be shipped under Official FDA seal (i.e., FDA 415a). An example of a FDA Official Seal has been incorporated below.



2. All information available to FDA/CFSAN regarding choking/aspiration/ingestion hazard injuries related to the products submitted, or similar products.

B. CPSC shall provide:

1. Verbal/or written choking hazard evaluations for each konjac gel-containing type candy product provided by FDA/CFSAN within 10 working days of receipt of the samples. It is estimated that approximately 4 hours of CPSC staff time will be needed to process each sample, provide written reports, and engage in related telephone discussions with FDA/CFSAN. This agreement will apply to the first 20 samples processed by CPSC staff prior to the end of the current fiscal year (September 30, 2002). The agreement will require renewal at the end of the fiscal year. If more than 20 samples are submitted for evaluation by FDA/CFSAN in any one fiscal year, the terms of the contract will require revision.

2. At the request of FDA/CFSAN, and at the CPSC management's discretion as to the availability of HS Physiologists, attendance at local meetings (Washington, DC area), or participation in teleconference calls related to the choking hazard potential of konjac gel-containing candy products.

3. At the request of FDA/CFSAN, a CPSC physiologist from CPSC's Directorate for Health Science who will be available to provide technical support and serve as an expert witness in support of any ensuing FDA/CFSAN litigation procedures pertinent to the choking hazard potential of konjac gel-containing candies and related products. All associated costs and expenses will be covered by FDA/CFSAN (See Funding, Section XII. B. - 1 and 2).

C. CPSC will not be required to return any remaining portions of product samples, as CPSC will only be provided with a portion of the FDA/CFSAN official sample.

VI. Disclosure of Information:

The samples submitted to CPSC will be evaluated for their relative choking hazard potential. The CPSC staff may not disclose any information concerning the evaluations to anyone outside of the CPSC or FDA without the express written permission of FDA/CFSAN. In accordance with 21 C.F.R. § 20.62 (nondisclosure to the public of inter- or intra-agency memoranda or letters) and 21 C.F.R. § 20.64 (nondisclosure to the public of records or information compiled for law enforcement purposes, including "all records relating to regulatory enforcement action, including both administrative and court action, which have not been disclosed to any member of the public, including any person who is subject of the investigation"). The CPSC HS Physiologists shall submit to FDA/CFSAN any report, manuscript, or other document containing the results of work performed under this Agreement before such document is published or otherwise disclosed to the public. This submission will assure that there is no pending investigation or other activity associated with the evaluated samples that could be compromised.

Any publications of, or publicity pertaining to, the work performed under this Agreement shall include the following:

"This project includes or is based on information provided by staff of the U.S. Consumer Product Safety Commission. The content of this publication does not necessarily reflect the views of the Commission, nor does mention of trade names, commercial products, or organizations imply endorsement by the Commission."

VII. CPSC Project Officer:

CPSC PROJECT OFFICER: Sandra E. Inkster, Ph.D.
Telephone: (301) 504-0994 ext. 1198
E-mail: sinkster@cpsc.gov

Consumer Product Safety Commission
Directorate for Health Sciences
Room 600-20
Washington, D.C. 20207

VIII. FDA/CFSAN Financial Officer:
AGENCY PAYMENT OFFICER: Barbara Gautreaux.
Telephone: (301) 436-1742
E-mail: Bgautreaux@cfsan.fda.gov

IX. FDA Project Manager:

FDA PROJECT MANAGER: Mark Hackman
Telephone: 301-827-7527
E-mail: Mhackman@cvm.fda.gov

Center for Food Safety and Applied Nutrition
Case Processing Branch, HFS-607
Office of Field Programs
Division of Enforcement and Programs
5100 Paint Branch Parkway
College Park, MD 20740-3835

X. Period of Agreement:

From date of fully executed agreement through September 30, 2002, to be renewed each fiscal year for as long as remains agreeable to both parties.

XI. Disagreements

In the event that CPSC and FDA/CFSAN have a disagreement arising under this interagency agreement, the parties shall cooperatively seek to resolve the disagreement by themselves. If the disagreement cannot be resolved between them, the parties agree to seek the assistance of a third party in resolving the disagreement.

XII. Funding:

A. Basis and Estimated Cost of Providing Sample Evaluations

Sample evaluations will be billed at $250 per sample, which is based on the average hourly rate of pay of CPSC Physiologists, including all benefits and overheads factors.

FDA/CFSAN estimates that up to 10 evaluations may be required at this time, with a total cost not to exceed ($2,500.00). Advance funding in the amount of $2,500.00 is being provided at this time.

B Basis and Estimated Costs of Providing Expert Testimony on Choking Hazard

1. The cost of employee time for providing expert witness testimony (including depositions and trials) will be charged at $500 per day, according to the number of complete or partial days that the CPSC Physiologist is required to be on duty as an FDA expert witness, or be in related travel status.

2. In addition, all CPSC Physiologists' travel-related expenses associated with providing expert witness testimony, including, but not limited to, airfare, taxi, hotels, meals, parking, etc, will be paid for by FDA/CFSAN. Travel arrangements will be handled by FDA, by issuance of travel orders. Where air travel is needed, tickets will be purchased by FDA, and the airport of flight origin will be subject to the convenience and approval of the testifying CPSC Physiologist. The CPSC Physiologist will submit to FDA/CFSAN travel vouchers to claim all travel expenses other than flight costs.

C. Billing

CPSC will provide the FDA/CFSAN Agency Payment Officer (see Section VIII) by September 15, 2002, with an accounting of funds expended for the cost of choking evaluations performed, and the cost of personnel for litigation support and related travel expenses. CPSC will return to FDA/CFSAN any unobligated funds pertaining to this agreement at least 15 days before the end of the fiscal year.

CPSC will advise FDA/CFSAN as soon as possible when advance funding nears depletion. Once advance funding is fully expended, no further work will be conducted for FDA/CFSAN by CPSC staff until new funding arrangements are made.

XIII. Funding and Accounting Data:

The transfer of funds should be through the On-Line Payment and Collection (OPAC) system using the following accounting data:

TRANSFER FROM:

FDA/CFSAN Accounting and Appropriation Data:

Appropriation: 7520600
CAN: 2-6991990-F-63342
PMS: 223152/10
Object Class: 25.38
Agency Location no: 75060099

TRANSFER TO

CPSC Accounting and Appropriation Data: 02-SA EXOB 4500 22560 111a

Appropriation: 6120100
Object Class: 111a & 219b
Agency Location number: 61000001

XIV. Authority:

A. FDA Authority: Economy Act of 1932, as amended 31 U.S.C. §1535;

B. CPSC Authority: Section 27(g) of the Consumer Product Safety Act, 15 U.S.C. § 2076(g);

XV. FASA Compliance:

As the servicing agency, CPSC agrees to act in full compliance with Section 1074 of the Federal Acquisition Streamlining Act (FASA) of 1994 entitled ECONOMY ACT PURCHASES.